

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

10/542501

Applicants: **Ronald W. Wood**

U. S. Serial No: **To be assigned**

Filed: **Herewith**

PCT International
Application No: **PCT/US2004/000961**

Filed: **15 January 2004**

For : **QUATERNARY ANTIMUSCARINIC
COMPOUNDS FOR THE TREATMENT OF
BLADDER DISEASES**

INFORMATION DISCLOSURE STATEMENT

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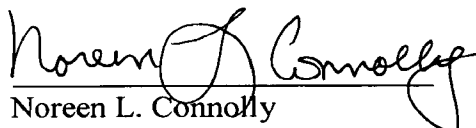
In compliance with 37 C.F.R. 1.56, 1.97, and 1.98, applicants hereby bring to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO-1449 form. Published art included in the International Search Report (copy enclosed) of the corresponding PCT application, is cited for consideration and listed on the enclosed PTO-1449 form as reference numbers 3-5, 15, and 26. These references are relevant for the reasons given in the search report.

Because copies of the references indicated in the International Search Report should have been transferred by the International Searching Authority ("ISA"), duplicate copies are not enclosed herewith. Should the U.S. Patent and Trademark Office ("PTO") require a copies of the references from applicants (i.e., the ISA has not provided them), the PTO should contact the undersigned representative directly.

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Respectfully submitted,

Date:

July 14, 2005

Noreen L. Connolly
Registration No. 48,987

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Receipt date: 07/14/2005

10/542501 GAU: 1614

PTO/SB/08A (10-01)

Approved through 10/31/2002. OMB 0651-0031

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Substitute for form 1449A/PTO				Application Number		To Be Assigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Filing Date		Herewith
				First Named Inventor		Ronald W. Wood
				Art Unit		To Be Assigned
				Examiner Name		To Be Assigned
				Attorney Docket Number		176/61373 (6-11407-1177)*
Sheet	1	of	4			

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	1	US-5,001,160	03/19/1991	McPherson et al.	
	2	US-5,552,407	09/03/1996	Wood et al.	
	3	US-5,610,163	03/11/1997	Banholzer et al.	
	4	US-5,654,314	08/05/1997	Banholzer et al.	
	5	US-5,770,738	06/23/1998	Banholzer et al.	
	6	US-5,821,249	10/13/1998	Wood et al.	
	7	US-6,482,837	11/19/2002	Wood	
	8	US-6,573,282	06/03/2003	Yaksh et al.	
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FOREIGN PATENT DOCUMENTS						
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
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	9	"Anticholinergic Therapy: The State of the Art. Proceedings of a Symposium Held in Stratford-Upon Avon 8-9 September 1986," Higgenbottom et al., eds., <i>Postgrad. Med. J.</i> 63(Suppl 1):1-86 and Poster Abstracts and Discussion 63(Suppl 1):1A-31A (1987)	
	10	Autret et al., "Plasma Levels of Oxybutynine Chloride in Children," <i>Eur. J. Clin. Pharmacol.</i> 46:83-85 (1994)	
	11	Barbalias, G.A., "Interstitial Cystitis: Bladder Training with Intravesical Oxybutynin," <i>J. Urol.</i> 163:1818-1822 (2000)	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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JC18 Rec'd PCT/PTO 14 JUL 2005 - GAU: 1614

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	To Be Assigned
				Filing Date	Herewith
				First Named Inventor	Ronald W. Wood
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	4	Attorney Docket Number	176/61373 (6-11407-1177)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	12	Brendler et al., "Topical Oxybutynin Chloride For Relaxation of Dysfunctional Bladders," <i>J. Urol.</i> 141:1350-1352 (1989)	
	13	Brown et al., "Proceedings of the National Institute of Diabetes and Digestive and Kidney Diseases International Symposium on Epidemiologic Issues in Urinary Incontinence in Women," <i>Am. J. Obstet. Gynecol.</i> 188:S77-S88 (2003)	
	14	Chen et al., "Pulmonary Effects of the Cocaine Pyrolysis Product, Methylecgonidine, in Guinea Pigs," <i>Life Sciences</i> 56(1):7-12 (1995)	
	15	Davilla, G.W., "Advances in Anticholinergic Therapy Delivery Systems," <i>Urology Times</i> , pp. 1-2 (June 2002)	
	16	Disse et al., "Ba 679 BR, A Novel Long-Acting Anticholinergic Bronchodilator," <i>Life Sciences</i> 52:537-544 (1993)	
	17	Disse et al., "Tiotropium (Spiriva TM): Mechanistical Considerations and Clinical Profile in Obstructive Lung Disease," <i>Life Sciences</i> 64(6/7):457-464 (1999)	
	18	Eichel et al., "Assessment of Murine Bladder Permeability with Fluorescein: Validation With Cyclophosphamide and Protamine," <i>Urology</i> 58(1):113-118 (2001)	
	19	El-Fawal et al., "Airway Smooth Muscle Relaxant Effects of the Cocaine Pyrolysis Product, Methylecgonidine," <i>J. Pharm. Exp. Ther.</i> 272(3):991-996 (1995)	
	20	Gearien, J.E., "Cholinergics, Acetylcholinesterases, and Antispasmodics," Foye, W.O., eds., <i>Principles of Medicinal Chemistry</i> , Lean and Febiger, Philadelphia, PA, Chapter 15, pp. 323-341 (1989)	
	21	Franztz et al., "Implementing an Incontinence Management Protocol in Long-Term Care," <i>J. Gerontological Nursing</i> 29(8):46-53 (2003)	
	22	Heller et al., "Muscarinic Receptor Agonists and Antagonists," Goodman and Gilman, <i>The Pharmacological Basis of Therapeutics</i> , 10 th Edition, Hardman et al., eds., McGraw-Hill, Chapter 7, pp. 155-173 (2000)	
	23	Green et al., "Urinary Incontinence in Subacute Care - A Retrospective Analysis of Clinical Outcomes and Costs," <i>MJA</i> 178:550-553 (2003)	
	24	Greenfield et al., "The Use of Intravesical Oxybutynin Chloride in Children with Neurogenic Bladder," <i>J. Urol.</i> 146:532-534 (1991)	

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				First Named Inventor	Ronald W. Wood
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	25	Gross, H.J., "Ipratropium Bromide," <i>New. Eng. J. Med.</i> 319:486-494 (1988)	
	26	Hay-Smith et al., "Anticholinergic Drugs Versus Placebo for Overactive Bladder Syndrome in Adults," <i>Cochrane Database Syst. Rev.</i> 3:CD003781 (2002) (Abstract)	
	27	Hogan, D.B., "Revisiting the O Complex: Urinary Incontinence, Delirium and Polypharmacy in Elderly Patients," <i>Can. Med. Assoc. J.</i> 157(8):1071-1077 (1997)	
	28	Hu et al., "Estimated Economic Costs of Overactive Bladder in the United States," <i>Urology</i> 61(6):1123-1128 (2003)	
	29	Krishnan, K.R., "A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multicenter Study of Intravesical Oxybutynin," <i>Neurourol. And Urodyn.</i> 15:307-308 (1996) (Abstract #32)	
	30	Langtry et al., "Terodiline. A Review of its Pharmacological Properties, and Therapeutic Use in the Treatment of Urinary Incontinence," <i>Drugs</i> 40(5):748-761 (1990)	
	31	Madersbacher et al., "Control of Detrusor Hyperreflexia by the Intravesical Instillation of Oxybutynine Hydrochloride," <i>Paraplegia</i> 29:84-90 (1991)	
	32	Martin et al., "Pyrolysis and Volatilization of Cocaine," <i>J. Anal. Toxicol.</i> 13:158-162 (1989)	
	33	Norman et al., "Tiotropium Bromide, Treatment of COPD Bronchodilator Muscarinic Antagonist," <i>Drugs of the Future</i> 25(7):693-699 (2000)	
	34	Olesen et al., "Calcitonin Gene-Related Peptide Receptor Antagonist BIBN 4096 BS for the Acute Treatment of Migraine," <i>N. Engl. J. Med.</i> 350(11):1104-1110 (2004)	
	35	Pietzko et al., "Influences of Trosipium Chloride and Oxybutynin on Quantitative EEG in Healthy Volunteers," <i>Eur. J. Clin. Pharmacol.</i> 47:337-343 (1994)	
	36	Scheidweiler et al., "Pharmacokinetics and Pharmacodynamics of Methylecgonidine, a Crack Cocaine Pyrolyzate," <i>J. Pharm. Exp. Ther.</i> 307(3):1179-1187 (2003)	
	37	Sessions et al., "Continuous Bladder Infusion Methods for Voiding Function in the Ambulatory Mouse," <i>Urology</i> 60(4):707-713 (2002)	

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	38	Shih et al., "Labor Costs Associated with Incontinence in Long-Term Care Facilities," <i>Urology</i> 62(3):442-446 (2003)	
	39	Takahashi et al., "Effect of Ba 679 BR, A Novel Long-Acting Anticholinergic Agent, On Cholinergic Neurotransmission in Guinea Pigs and Human Airways," <i>Am. J. Resp. Crit. Care Med.</i> 150:1640-1645 (1994)	
	40	Thuroff et al., "Randomized, Double-Blind, Multicenter Trial on Treatment of Frequency, Urgency and Incontinence Related to Detrusor Hyperactivity: Oxybutynin Versus Propantheline Versus Placebo," <i>J. Urol.</i> 145:813-817 (1991)	
	41	Ukimura, O., "Effects of Intravesically Administered Anticholinergics, β -Adrenergic Stimulant and α -Adrenergic Blocker on Bladder Function in Unanesthetized Rats," <i>Tohoku J. Exp. Med.</i> 170:251-260 (1993)	
	42	Weese et al., "Intravesical Oxybutynin Chloride: Experience With 42 Patients," <i>Urology</i> 41:527-530 (1993)	
	43	Willetts et al., "Effects of Methylecgonidine on Acetylcholine-Induced Bronchoconstriction and Indicators of Lung Injury in Guinea Pigs," <i>Life Sciences</i> 57(15):225-230 (1995)	
	44	Witek, T.J. Jr., "Anticholinergic Bronchodilators," <i>Respiratory Clinica of North America</i> 5:521-536 (1999)	
	45	Wood et al., "Automated Noninvasive Measurement of Cyclophosphamide-Induced Changes in Murine Voiding Frequency and Volume," <i>J. Urol.</i> 165:653-659 (2001)	
	46	Wood et al., "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity," <i>Pharmacology, Biochemistry & Behavior</i> 55(2):237-248 (1996)	
	47	Wood et al., "Uroflow in Murine Urethritis," <i>Research Insights into Interstitial Cystitis: A Basic and Clinical Science Symposium</i> , Alexandria, VA, October 30-November 1, 2003; co-presented by the National Institute of Diabetes and Digestive and Kidney Diseases and the Interstitial Cystitis Association (Abstract and Poster Presentation) (2 pp.)	

Examiner Signature	/Brian Yong Kwon/	Date Considered	11/12/2008
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